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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,918	09/05/2003	Robin M. Forbes Jones	TAV-2044	8375

7590 06/13/2011

Patrick J. Viccaro, Esquire
Allegheny Technologies Incorporated
1000 Six PPG Place
Pittsburgh, PA 15222-5479

EXAMINER	
ROE, JESSEE RANDALL	
ART UNIT	PAPER NUMBER
1733	

MAIL DATE	DELIVERY MODE
06/13/2011	PAPER

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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Ex Parte ROBIN M. FORBES JONES, HENRY E. LIPPARD, TIMOTHY A. STEPHENSON, ROBERT J. MYERS, *and* DAVID J. BRADLEY

Appeal 2010-006845
Application 10/656,918
Technology Center 1700

Oral Hearing Held: May 10, 2011

Before CATHERINE Q. TIMM, BEVERLY A. FRANKLIN, and MICHAEL P. COLAIANNI, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

MARK R. LESLIE, ESQUIRE
K&L Gates, LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, Pennsylvania 15222-2613

The above-entitled matter came on for hearing on Tuesday, May 10, 2011, commencing at 1:29 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Dominico Quattrociocchi, a Notary Public.

PROCEEDINGS

THE USHER: Good afternoon. Calendar Number 25, Appeal Number 2010-6845, Mr. Leslie.

JUDGE TIMM: Thank you.

Good afternoon, Mr. Leslie. Welcome to the Board.

MR. LESLIE: Thank you.

JUDGE TIMM: Are the gentlemen in the back part of your group?

MR. LESLIE: Yes, they are.

JUDGE TIMM: Could you introduce them for us?

MR. LESLIE: Yes. This is John Grosselin. He's the counsel for the Assignee. And --

MR. COX: I'm Adam Cox representing Fort Wayne Metals Research Corporation, and this is Jerry Pfister, General Counsel of Fort Wayne Metals.

MR. LESLIE: They're co-owner. Yes.

JUDGE TIMM: Thank you, and welcome to the Board.

Mr. Leslie, if you could state your name and the law firm you're with for the court reporter, that would be appreciated.

MR. LESLIE: Mark R. Leslie with K&L Gates.

JUDGE TIMM: Okay. And as you can see, one of our Judges is with us electronically today. And you have 20 minutes and you may begin when you're ready.

MR. LESLIE: Okay, thank you. There are a number of issues involved in this case, and with the short amount of time that I have I'd just like to address what I think are a few important issues in the case, and I'll address these seriatim

But the first issue that I'd like to point out is that part of the invention here is that the Inventors discovered a problem. They discovered that it was the morphology and the shape of the microstructure in the alloy, the conventional MP35N alloy, that was disadvantageous in terms of the fatigue resistance of the alloy. Once they discovered that, they set upon the task of modifying the alloy to try to address the microstructure and improve the fatigue resistance. So they adjusted the alloy's microstructure -- or, sorry, adjusted the alloy's composition, and that's reflected in Claim 1 in this case. And when they did that, the resulting microstructure was very substantially different. The resulting microstructure was small, spherical, oxide inclusions whereas the microstructure and the conventional material was including titanium nitride and mixed metal carbonitride inclusions that were large and cuboidal, and what the Inventors discovered is that the large cuboidal microstructure was negatively affecting the fatigue resistance of the alloy. So what they discovered was that they created a completely different microstructure, but also that the fatigue resistance of the material after the microstructure changed was greatly improved, and we've set out that data and -- in declaratory form in the Appeal.

Now, the basis for the rejection here, the primary basis for rejecting Claim 1 is that the claim would have been obvious over the *Smith* reference taken alone. One of the points that we set out in our Appeal and in the Reply is that *Smith* does not teach or suggest a nitrogen content that's less than 30 PPM, which is part of the composition recited in the claim. We've shown in declaratory evidence that was submitted in the case that *Smith* would have included -- the alloy of *Smith* would have included at least 50 parts per million nitrogen, which the declaration from *Lippard* shows would have been in the minimal level of nitrogen in any conventional MPN -- or MP35N alloy. Moreover, the *Smith* reference lacks any teaching or suggestion as to why one would seek to undertake the steps to reduce the nitrogen content in the alloy in that reference. And as I noted, it's also uncontradicted in the file history that the present Inventors were the persons who discovered the problems associated with the size and the morphology of the inclusions in the conventional MP35N alloy.

The Examiner takes the position that *Smith* teaches as little as zero nitrogen, but the only thing that *Smith* says regarding nitrogen is as follows. "It is critically important that the alloy composition contain no more than 0.05 percent, which is equivalent to 500 PPM of carbon, boron, oxygen, nitrogen, or beryllium." *Smith* doesn't point to anything particularly important about nitrogen or any motivation or suggestion that nitrogen should be reduced.

JUDGE TIMM: But it seems to me like that is disclosing that those are particular impurities that are not desirable in the alloy.

MR. LESLIE: I agree. I believe that what that teaching is it's setting forth what would be the maximum amount of certain incidentals. But our

position is that what we have is an alloy that has very little nitrogen and requires positive and costly steps in order to reduce the nitrogen in the alloy, and those steps would include, for example, using very pure starting materials, probably melting the alloy and vacuum, et cetera.

JUDGE TIMM: And it's your position that *Smith* wouldn't have undergone those costly steps?

MR. LESLIE: Well, unless there was some motivation or suggestion to do so. If you look at the examples in *Smith*, for example, there's nothing in there that indicates that the nitrogen was particularly low. Our expert has stated that the nitrogen, at minimum, would have been 50 PPM in an MP35N alloy.

JUDGE TIMM: And is the *Smith* that type of an alloy? Has it been established --

MR. LESLIE: That's what I understand, yes. There are various manufacturers that make different types of MP35N alloy, but they fall within the broad general composition in *Smith*, the conventional alloys.

JUDGE FRANKLIN: Is there anything in *Smith* that would suggest that it's that type of alloy?

MR. LESLIE: I don't believe so. I think that was probably one of the seminal patents, so it hadn't been identified as an MP35N alloy at that point, But what *Smith* discloses is a cobalt-nickel-chrome-moly alloy with the general composition or broad composition in which an MP35N alloy would fall within. But there's no specific teaching in *Smith* and there's no evidence of record that would indicate any need to reduce nitrogen to less than a normal level in this particular alloy. Then again, it was the Inventors that discovered the problem here and attempted to remedy the problem by

reducing the nitrogen content, among other things. It's not just the reduction in nitrogen content, it was also a reduction in titanium and the addition of minor but critical amounts of deoxidizing elements, aluminum, calcium, magnesium, and/or cerium, and the result was the synergy between all of these particular modifications that resulted in alloy with a fundamentally different microstructure and that also had unexpected and surprising results in terms of greatly improved fatigue resistance.

And we point out in the application, and also in the papers that we filed, that fatigue resistance is particularly critical in these applications that the alloy is used for because it's used in medical implants, including stints and guide -- or not guidewires, but wires for cardiac pace makers and defibrillators. So when these wires are in the body, they are constantly fatigued and stressed by movement of the body and the beating of the heart, so any premature failure through fatigue is particularly critical here.

JUDGE TIMM: Does the *Smith* --

JUDGE FRANKLIN: Do you have evidence in the record that connects what you claim, for example, less than 30 parts per million nitrogen, that's critical to the morphology?

MR. LESLIE: Well, we -- yes, we do have evidence in the application itself showing the morphology, the shape and the size of the inclusions in a conventional MP35N alloy, which would have included more than 50 PPM nitrogen, and then the modified alloy that falls within Claim 1. It shows that the shape of the inclusions are different, their size, and also shows that the fatigue resistance and the endurance limit were much greater for the modified alloy when it was drawn down to a very small wire.

JUDGE FRANKLIN: I have a question in regard to the specification.

MR. LESLIE: Yes?

JUDGE FRANKLIN: In paragraph 37, it talks about what you referred to as the conventional MP35N alloy -- this is on page 11 of the specification -- but then it seems to indicate that the levels of nitrogen in the examples were not determined, but on the other hand, I guess you argue that it's known that it would be 50 parts per million.

MR. LESLIE: Yes. That's set forth in a declaration, an expert declaration, actually, an inventor declaration that was filed in the case. It's the declaration of Henry Lippard, a Ph.D. who works for ATI, Allegheny Technologies.

JUDGE FRANKLIN: Yes. In the declaration, it does talk about that. However, there seems to be a contradiction --

MR. LESLIE: Okay.

JUDGE FRANKLIN: -- between what's in paragraph 37, where it says of levels of nitrogen were not determined, versus, the statement in the declaration. How do we know what the level of nitrogen is in that standard alloy at Table 9?

MR. LESLIE: We have been -- in Table 2, we set forth the chemistry of the samples that were tested and we do have nitrogen contents for the experimental heat.

JUDGE FRANKLIN: Table 2 does not list the nitrogen?

MR. LESLIE: It does not list the nitrogen because it was a conventional level of nitrogen, so it was not tested for the material, but the declaration supports that it would have been at least 50 PPM.

Another issue that's in the case is whether the decision, *Atofina*, would apply to this case as a case where we have overlap or encompassment

of ranges with the ranges in a reference. And we include a table in the Reply Brief that shows the extent of overlap between the broad alloy that is described in *Smith* and the much narrower composition that's recited in Claim 1, and our position is that *Adafina*, which is a case that dealt with encompassment or overlap or ranges, should be applied here because, essentially, what we have is a species for an -- versus genus situation where we have a very broad disclosure in the reference that's relied upon the Examiner, and we have a narrower, a much narrower set of ranges of elements in the claimed invention, and the Examiner takes the position, which I think is set out in the MPEP, that *Atofina* only applies in anticipation situations. But what we submit is that *Atofina* really provides a framework for looking at references versus claimed inventions when you have a situation that's akin to a species versus genus, so it provides a useful framework for analyzing whether, in fact, a prima facie case of obviousness has been established.

And I also note that in a recent decision by the Board, *Ex Parte Dutton* 2009-14442, on September 1st, 2010, the Board indicated that the extent of overlap should be considered when determining whether a -- whether there is a prima facie case of obviousness established, and in that *Ex Parte Dutton* decision, the Board stated "although each case must be evaluated on its own facts, the mere disclosure of a broader range is not an anticipation of a narrower range within the broader range. *See Atofina.* Indeed, such a limited disclosure does not necessarily suffice to establish a prima facie case of obviousness." And then citing *In Re Jones* in which the Federal Circuit stated that "we decline to extract from *Merck,*" which is a 1989 Federal Circuit decision, "the rule that the solicitor appears to suggest,

that regardless of how broad a disclosure of a chemical genus, renders obvious any species that happens to fall within it." So our position is that *Atofina* provides a framework that can be applied when considering whether a prima facie case of obviousness has been established when there's overlap between ranges and the overlap between broad ranges in a reference and ranges in a claimed alloy are relatively insignificant.

Now, the Examiner addressed the species versus genus type of situation in the Answer and suggests in the Answer that regardless of any genus species distinction, the rejection of Claim 1 is appropriate because one would have been motivated to optimize the broad composition of *Smith* and achieve the alloy composition recited in the claims. And what the Examiner argued is that the normal desire of scientists and artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages, and it's citing to MPEP 2144.05. So the Examiner, apparently, was asserting that one having ordinary skill, without knowledge of the invention, and also without having first discovered the problem that the Inventors discovered, would have optimized the up to 0.05 nitrogen range of *Smith* to achieve the recited range that's less than 30 PPM. But it's our position that one having ordinary skill in the art, without knowledge of the invention, as is appropriate, and without knowledge of the Inventors' discovery of the disadvantages of the titanium nitride and mixed metal carbonitride inclusions, would have had no incentive to investigate criticalities associated with nitrogen or with any of the other incidentals that were listed in the sentence that's extracted from *Smith* that say's it's

critically important that the alloy contain no more than 0.05 percent or 500 PPM of each of these elements.

One additional issue that I'd like to address would be the issue of inherency, and the Examiner, apparently, relies on inherency as providing the microstructure of the alloy in the claim because the *Smith* reference, which is the sole reference that's cited against Claim 1, does not say anything about microstructure. It does not disclose the microstructure that's recited in Claim 1 and which was determined to be critical to the greatly improved fatigue resistance. In the Answer, the Examiner relies upon MPEP 2112 in filling in this gap, and 2112 is the inherency section of the MPEP. But if you look at the microstructure, it was a result of very specific elemental ranges that worked in synergy to produce an entirely different microstructure. And so, there is no indication in *Smith* that any particular microstructure like this was important and there would have existed no reason on the part of one of skill in the art at that time to essentially optimize all of the ranges that one would have need to optimize in *Smith* to achieve the claimed invention. So under those circumstances, it would only -- you would only happen upon the invention by varying every parameter of the system that's described in *Smith*, with no reason to select which parameters to vary or how much to vary them, to end up with an alloy that was as claimed in the case here.

So, essentially, the way I like to look at it is you have a number of dials, each of the dials relates to a particular element, and the Examiner takes the position that it would have been obvious to turn all of the dials to optimize in a way that would achieve the invention, but our position is that unless you have some motivation or suggestion why you would want to turn

those dials or in which direction and what result you would want to achieve, you haven't established that it would have been obvious to optimize all of those particular parameters. And in the case *In Re Reichardt* (ph.), Federal Circuit 93, it stated that, thus, there is only a possibility or small probability that such a microstructure would be present in the prior art as opposed to a certainty, and that makes the microstructure not inherent. So inherency, which the Examiner relies upon to supply the microstructure, is not an appropriate principle to be relied upon in an obviousness rejection.

Now, in addition to those issues which address the prima facie rejection, we also have submitted a lot of evidence of secondary considerations to rebut any prima facie case that may have been established. And I don't know that we've gotten much in the way of feedback from the Examiner on any problems with the evidence that we have submitted, which I consider to be rather significant by showing the great improvement in fatigue resistance. The only thing that the Examiner said in the Answer was that at one data point, 250 KSI, there was an improvement for the conventional material relative to the modified material. And what we've shown in the Reply, really, the critical fatigue level here is at 100 KSI, which closely replicates what would happen in the body, and at 100 KSI, the number of cycles that the material, the modified material of Claim 1 achieved was almost 800 times -- or 800 percent greater than the number of cycles that was achieved by the conventional material. So what this equates to is a material that is much less likely to fail and has a much improved service life, which is particularly important here given the critical applications that this material is used in.

Not surprisingly, we also submitted evidence that there is great commercial success in selling this material to device manufacturers and the end-over-end increase sales in the period that we submitted -- I think that we had submitted that evidence back in '07 -- the increases in sales were particularly important and were particularly great. And we also submitted evidence that the reason for that -- or a major reason for that was that the purchasers knew that the fatigue resistance of the material was significantly better than the existing material, which they consider particularly important given the applications.

JUDGE TIMM: Did you submit any --

JUDGE FRANKLIN: Is any of the evidence --

Oh, sorry.

JUDGE TIMM: Go ahead, Beverly.

JUDGE FRANKLIN: I just wanted to know if any of that evidence can -- was directed to the market share.

MR. LESLIE: No, we did not have market share evidence.

JUDGE FRANKLIN: And your Assignee, is it a large company? Can you describe its size?

MR. LESLIE: Well, the company that I represent, Allegheny Technologies, makes the alloy and sells it to Fort Wayne Metals, who then draws the alloy to a thin gauge wire and sells the wire. So the evidence that we submitted was sales data supplied to us by Fort Wayne Metals for the lineal feet of wire that they're selling year per year.

JUDGE FRANKLIN: And the size of your company? You --

MR. LESLIE: Well, the size of Allegheny Technologies is approximately 3- to 5 billion in sales per year. Fort Wayne Metals --

Do you know, sales for Fort Wayne Metals?

MR. COX: Just over 100 million gross.

MR. LESLIE: -- over a 100 million gross for Fort Wayne. I mean, these are large companies and the sales of this material, I think, was in excess of several million lineal feet in the last year of the data that we supplied. And the anecdotal evidence supplied to the person responsible for sales at Fort Wayne Metals was that customers were shifting over from normal conventional MP35 material to thin gauge wire made from this new modified alloy because of its improved fatigue resistance.

JUDGE TIMM: So the market basically consists of this MP3, the conventional, and your modified --

MR. LESLIE: Yes.

JUDGE TIMM: -- to market for this material?

MR. LESLIE: Yes, for the applications used in cardiac pacemakers leads and wires.

I've covered everything that I want to cover. Does anybody have any questions?

JUDGE TIMM: No.

JUDGE FRANKLIN: Yes, one more question with regard to the amount of claimed nitrogen and titanium. You mentioned you had to have the -- or suggest the criticality of that with regard to the morphology. Do you also have evidence of criticality with regard to the fatigue resistance?

MR. LESLIE: Well, we --

JUDGE FRANKLIN: -- that claim, right?

MR. LESLIE: Yeah, we don't include anything in the claim that speaks of fatigue resistance, but the evidence that we submitted does

compare a conventional MP35 alloy drawn to seven-thousandths diameter wire and an alloy that falls within Claim 1 drawn to the same diameter wire and then tested on a rotary beam fatigue tester for fatigue resistance and fatigue limit. So it's a direct comparison of those two samples.

JUDGE FRANKLIN: What was the amount of nitrogen in the inventive -- in your sample?

MR. LESLIE: The amount of nitrogen. It was less than 30 PPM.

JUDGE FRANKLIN: So it represented one value of the claim range?

MR. LESLIE: Yes. I mean, what I'd like to point out though is we haven't had any feedback from the Examiner regarding the quality of the evidence that we submitted. Instead, the Examiner just takes issue with this one data point that was extracted at 250 KSI where an improvement is not shown. But the argument that we've presented in the Reply Brief is that 250 is not really an important place to test this material because in actual service, it's subjected to a lower fatigue level of 100 KSI and it's subjected to, over its lifetime, perhaps several million fatigue cycles.

JUDGE TIMM: Any further questions? Judge Franklin?

JUDGE FRANKLIN: No further questions.

JUDGE TIMM: Judge Colaianni?

JUDGE COLAIANNI: No questions.

JUDGE TIMM: Well, I think we understand the issues in the case and we thank you for coming in.

MR. LESLIE: Thank you.

JUDGE TIMM: Thank you very much.

(Whereupon, the proceedings, at 1:55 p.m., were concluded.)